



#21

PTO/SB/08A (10-01)
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U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	09/585,645	
			Filing Date	June 1, 2000	
			First Named Inventor	Huda Y. Zoghbi	
			Art Unit	1633	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	HO-P01899US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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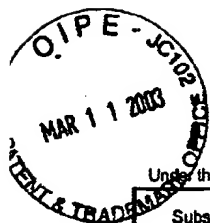
¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CA	✓	Ho, Alan, et al.; Synthetic Protein Transduction Domains: Enhanced Transduction Potential <i>in Vitro</i> and <i>in Vivo</i> ; Cancer Research, Vol. 61, pp 474 - 477, January 15, 2001	
CB	✓	Jero, Jussi, et al.; A surgical approach appropriate for targeted cochlear gene therapy in the mouse; Hearing Research, Vol. 151, pp 106 - 114, 2001	
CC	✓	Jero, Jussi, et al.; Cochlear Gene Delivery through an Intact Round Window membrane in Mouse; Human Gene Therapy; Vol. 12, pp 539 - 548, March 20, 2001	
CD	✓	Lalwani, Anil K., et al.; Expression of Adeno-Associated Virus Integrated Transgene Within the Mammalian Vestibular Organs; Am J Otol 19:390 - 395, 1998	
CE	✓	Staecker, Hinrich, et al.; Brain-derived neurotrophic factor gene therapy prevents spiral ganglion degeneration after hair cell loss; Otolaryngol Head Neck Surg 1998; 119:7 - 13	
CF	✓	Sherman, Michael P., et al.; HIV-1 Vpr Displays Natural Protein-Transducing Properties: Implications for Viral Pathogenesis; Virology 302, 95 - 105 (2002)	
CG	✓	Ford, K.G., et al.; Protein transduction: an alternative to genetic intervention? Gene Therapy (2001) 8, 1 - 4	
CH	✓	Morris, May C., et al.; A peptide carrier for the delivery of biologically active proteins into mammalian cells; Nature Biotechnology, Vol. 19, pp 1173 - 1176, December 2001	
CI	✓	Stöver, Timo, et al.; Cochlear gene transfer: round window versus cochleostomy inoculation; Hearing Research 136 (1999) 124 - 130	

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#24

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#30

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Complete If Known		
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			First Named Inventor	Huda Y. Zoghbi	
			Art Unit	1633	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	HO-P01899US2 (09906355)

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (If known)				
CA	BA	WO 00/27426	05/18/2000	Genentech, Inc.		
U	BB	WO 98/19700	05/14/1998	Genentech, Inc.		

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CA	CA	THIBODEAU, G.A., ET AL., <i>Sense of Hearing and Balance: The Ear</i> , Unit 3, Communication, Control & Integration, Anatomy & Physiology, 4 th Ed., 1999, pp. 454-455, Mosby Inc., St. Louis, MO, USA.				
	CB	KAWAMOTO, K., ET AL., <i>Math1 Gene Transfer Generates New Cochlear Hair Cells . . .</i> , The Journal of Neuroscience, 6/1/03, pp. 4395-4400, 23(11), Society for Neuroscience.				
	CC	SHOU, J., ET AL., <i>Robust generation of new hair cells in the mature mammalian inner ear . . .</i> , Molecular & Cellular Neuroscience, 2003, pp. 169-179, Vol. 23, Elsevier Science (USA).				
	CD	DOOLING, R.J., ET AL., <i>Recovery of hearing and vocal behavior after hair-cell regeneration</i> , Proc. Natl. Acad. Sci. USA, Psychology, Dec. 1997, pp. 14206-14210, vol. 94, The National Academy of Sciences.				
	CE	CAREY, J.P., ET AL., <i>Hair cell regeneration & recovery of the vestibuloocular reflex . . .</i> , Journal of Neurophysiology, Nov. 1996, pp. 3301-3312 + cover, vol. 76, no. 5, The American Physiological Society.				

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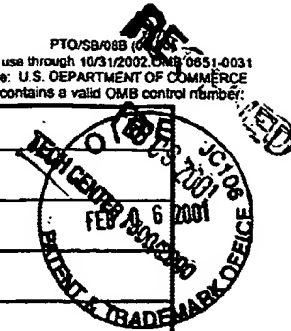
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PTO/SB/088 (Rev. 10/31/2002) OMB 0851-0031
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Substitute for form 1449/APTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete If Known		
			Application Number	09/585,645	
			Filing Date	June 1, 2000	
			First Named Inventor	Huda Y. Zoghbi	
			Group Art Unit	1644	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	4	Attorney Docket Number	HO-P01899US2



U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
CO		5,929,041		Magal	07-27-1999
		5,837,681		Magal	11-17-1998
		5,792,751		Ledley et al.	08-11-1998
		5,770,580		Ledley et al.	06-23-1998

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office ³	Number ⁴	Kind Code ⁵ (if known)		
CO		EP	0613945	A1	The General Hospital Corp.	09-07-1994
		WO	00/23084	A1	Kil	04-27-2000
		WO	99/42088	A1	Otogene AG	08-26-1999
		WO	99/06034	A1	Baylor College of Medicine	02-11-1999
		WO	99/06064	A1	Amgen, Inc.	02-11-1999
		WO	98/19700	A1	Genentech, Inc.	05-14-1998
		WO	98/00014	A1	The Regents of the Univ. of Calif.	01-08-1998
		WO	97/17983	A1	Cambridge Neuroscience, Inc., et al.	05-22-1997
		WO	95/19182	A1	Baylor College of Medicine	07-20-1995
		WO	98/13048	A1	Trustees of the Univ. of Penn.	04-02-1998

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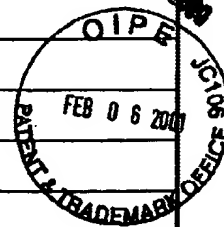
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
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CA	A	ZHENG JL ET AL., <i>Overexpression of Math1 induces robust production of extra hair cells in postnatal rat inner ears</i> ; Nature Neuroscience, Jun. 2000, pp. 580-586, vol. 3, no. 6, Nature America Inc.	
	B	EBERL DF, <i>Feeling the vibes: chordotonal mechanisms in insect hearing</i> , Current Opinion in Neurobiology, 1999, 9 pp.:in press.	
	C	AKAZAWA C ET AL., <i>A mammalian helix-loop-helix factor structurally related to the product drosophila proneural gene atonal is a positive transcriptional regulator expressed in the developing nervous system</i> , The Journal of Biological Chemistry; 04/14/95, pp. 8730-8738, vol. 270, no. 15, The American Society of Biochemistry & Molecular Biology, Inc.	
	D	SUN Y ET AL., <i>Transcriptional regulation of atonal during development of the drosophila peripheral nervous system</i> , Development 125, 1998, pp. 3731-3740, The Company of Biologists Limited, Great Britain	
	E	JARMAN AP ET AL., <i>Atonal is a proneural gene that directs chordotonal organ formation in the drosophila peripheral nervous system</i> , Cell, 07/02/93, pp. 1307-1321, vol. 73, Cell Press	
	F	HASSAN BA ET AL., <i>Doing the math: is the mouse a good model for fly development?</i> Genes & Development, 2000, pp. 1852-1865, vol. 14, Cold Spring Harbor Laboratory Press	
	G	HASSAN BA ET AL., <i>Atonal regulates neurite arborization but does not act as a proneural gene in the drosophila brain</i> , Neuron, Mar. 2000, pp. 549-561, vol. 25, Cell Press	
✓	H	BEN-ARIE N ET AL., <i>Math1 is essential for genesis of cerebellar granule neurons</i> , Nature, 11/13/97, pp. 169-172, vol. 390	
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	I	BERMINGHAM NA ET AL., <i>Math1: an essential gene for the generation of inner ear hair cells</i> , Science, 06/11/99, pp. 1837-1841, vol. 284, American Assoc. for the Advancement of Science
	J	BEN-ARIE N ET AL., <i>Functional conservation of atonal and Math1 in the CNS & PNS</i> , Development, 2000, pp. 1039-1048, vol. 127, The Company of Biologists Limited, Great Britain
	K	BEN-ARIE N ET AL., <i>Evolutionary conservation of sequence & expression of the bHLH protein Atonal suggests a conserved role in neurogenesis</i> , Human Molecular Genetics, 1996, pp. 1207-1216, vol. 5, Oxford Univ. Press
	L	JARMAN AP ET AL., <i>Atonal is the proneural gene for Drosophila photoreceptors</i> , Nature, 06/02/94, pp. 398-400, vol. 369
	M	KIM P ET AL., <i>XATH-1, a vertebrate homolog of Drosophila atonal, induces neuronal differentiation within ectodermal progenitors</i> , Developmental Biology, Article D8978572, 1997, pp. 1-12, vol. 187, Academic Press
	N	BEN-ARIE N ET AL., <i>Abnormal cerebellar development in mice lacking the murine homolog of the Drosophila proneural gene atonal</i> , American J. Human Genetics, 1996, vol. 59, no. 4, Suppl. p. A46, Abstract #232, see abstract
	O	SABATE O ET AL., <i>Adenovirus for Neurodegenerative diseases: in vivo strategies & ex vivo gene therapy using human neural progenitors</i> , Clinical Neuroscience, 1996, pp. 317-321, vol. 3, especially p. 317, rt. col., and p. 318, left col.
P	WILLIAMS DP ET AL., <i>Structure/Function analysis of Interleukin-2-toxin (DAB486-IL-2), fragment B sequences required for the delivery of fragment A to the cytosol of target cells</i> , J. Biol. Chem., 07/15/90, pp. 11885-11887, vol. 265, no. 20	
Q	CHIEN C-T ET AL., <i>Neuronal type information encoded in the basic-helix-loop-helix domain of proneural genes</i> , Proc. Natl. Acad. Sci. USA, Nov. 1996, pp. 13239-13244, vol. 93, especially pp. 13239-13240	
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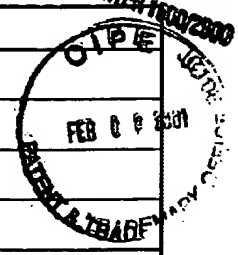
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CR ↓ ↓	R	SCHWARZE SR ET AL., <i>In vivo protein transduction: delivery of a biologically active protein into the mouse</i> , Science, 09/03/99, pp. 1569-1573, vol. 285, see entire document	
	S	VERMA IM ET AL., <i>Gene therapy-promises, problems & prospects</i> , Nature, 09/18/97, pp. 239-242, vol. 389, see entire document	
	T	LEDLEY FD, <i>Pharmaceutical approach to somatic gene therapy</i> , Pharmaceutical Research, Nov. 1996, pp. 1595-1614, vol. 13, no. 11, see entire document	
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ca	-	CHEN, P., JOHNSON, J.E. et al., The role of Math 1 in inner ear development: Uncoupling the establishment of the sensory primordium from hair cell fate determination, Development, 2002, pp. 2495-2505, vol. 129.	
	-	KANZAKI, S., KAWAMOTO, K. et al., From Gene Identification to Gene Therapy, Audiol. Neurotol., 2002, pp. 161-164, vol. 7.	
	-	KAWAMOTO K., OH, S.-H., et al., The Functional and Structural Outcome of Inner Ear Gene Transfer via the Vestibular and Cochlear Fluids in Mice, Molecular Therapy, December 2001, vol. 4(6).	
	-	ZHENG, J.L. AND GAO, W.-Q., Overexpression of Math1 Induces robust production of extra hair cells in postnatal rat inner ears, Nature Neuroscience, June 2000, pp. 560-566, vol. 3(6).	

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